REMARKS

Claims 1, 7, 17 to 21, 22 to 26, 30, and 33 to 37 are currently pending in this application. Claims 1, 7, 17 to 21, 25, 26, and 30 have been withdrawn by the Examiner. Claim 22 has been amended to track language recited in allowed claim 1 of U.S. Patent No. 6,699,966 (hereinafter "'966"), the parent to the present application. Specifically, claim 22 has been amended to recite a method of treating a patient by administering a composition comprising the substantially pure polypeptide complex recited in claim 1 of '966. New claims 33 to 37 have been added, which mirror claims 2 to 6 of '966. The amendments and new claims are supported throughout the specification and add no new matter.

35 USC §112, first paragraph

Claims 22 to 24 have been rejected as allegedly failing to comply with the written description requirement. Specifically, the Office Action (at page 3) alleges that the specification "does not describe a genus of variants for botulinum toxin type E neurotoxin associated polypeptides in the complexes, and the use of these complexes in the claimed method." Applicants respectfully disagree and submit that the originally-filed claims are in full compliance with the written description requirement. However, in the interest of moving the present application toward allowance, applicants have amended claim 22 to recite that the method includes administering to a patient a composition comprising a Clostridium botulinum neurotoxin and one or more Clostridium botulinum type E neurotoxin associated polypeptide selected from the group consisting of a polypeptide comprising the amino acid sequence of SEQ ID NO:4, a polypeptide comprising the amino acid sequence of SEQ ID NO:3, a polypeptide comprising the amino acid sequence of SEQ ID NO:2, a polypeptide comprising the amino acid sequence of SEQ ID NO:1, and a polypeptide comprising the amino acid sequence of SEQ ID NO:5. As acknowledged by the Office Action at page 3, these neurotoxin associated polypeptides are disclosed in the application. The amendment obviates the present rejection and applicants therefore request that it be reconsidered and withdrawn.

35 USC §112, second paragraph

Claims 22 to 24 were rejected as allegedly indefinite with regard to "what result a therapeutically effective amount of the polypeptide complex would produce in the treatment." (Office Action at page 4). Applicants respectfully traverse this rejection. Skilled practitioners would appreciate that the result of treatment would be a reduction in the symptoms of the disease being treated. The specification makes this clear, for example, at page 13, lines 13 to 15, which states:

> The dosage is adjusted, either in quantity or frequency, to achieve sufficient reduction in acetylcholine release to afford relief from the symptoms of the disease or condition being treated.

Claims 22 to 24 were also rejected as allegedly indefinite for recitation of the term "excessive release of acetylcholine." As an initial matter, applicants have amended claim 22 to recite "exaggerated release of acetylcholine." Applicants traverse this rejection because the specification clearly indicates what this term means, i.e., a level of release that exceeds the normal parameters and causes aberrant physiological function. It is clearly within the skill of practitioners in the field of medicine to determine normal parameters for acetylcholine release. The specification makes the meaning of this term clear and describes exemplary conditions associated with exaggerated release of acetylcholine, for example, at page 12, lines 6 to 17, which states:

> Those of skill in the art are aware of the normal parameters for acetylcholine release and of the normal range of physiological function that is produced when an appropriate amount of this neurotransmitter is released onto a muscle from adjacent nerve terminals. An exaggerated release of acetylcholine would be any level of release that exceeds the normal parameters and causes aberrant physiological function. The diseases or conditions associated with an exaggerated release of acetylcholine can involve spasms of either smooth or skeletal muscle cells. More specifically, these diseases or conditions include spasmodic torticollis, essential tremor, spasmodic dysphonia, charley horse, strabismus, blepharospasm, oromandibular dystonia, spasms of the sphincters of the cardiovascular, gastrointestinal, or urinary systems, and tardive dyskinesia, which may result from treatment with an anti-psychotic drug such as THORAZINE® or HALDOL®.

Claims 23 and 24 were rejected as allegedly indefinite for depending from a rejected claim, i.e., claim 22. Applicants submit that the amendments to claim 22 should obviate all of the present rejections which, in turn, should obviate the present rejection.

Claims 22 to 24 were rejected for depending from a non-elected claim. Applicants have amended claim 22 to be independent, thereby obviating this rejection.

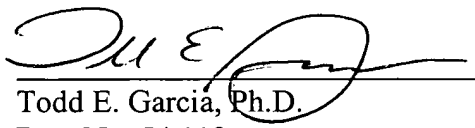
For the reasons discussed above, applicants submit that the metes and bounds of the claims are completely clear. Accordingly, applicants request that the all of these rejections be reconsidered and withdrawn.

CONCLUSION

Applicants request that all rejections be withdrawn and that all claims be allowed. Enclosed is a $510 check for the Petition for Extension of Time fee for a three-month extension. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 08387-002003.

Respectfully submitted,

Date: 2/22/07



Todd E. Garcia, Ph.D.
Reg. No. 54,112

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110
Telephone: (617) 542-5070
Facsimile: (617) 542-8906